STATE OF MICHIGAN
DEPARTMENT OF ENVIRONMENTAL QUALITY
LANSING

JENNIFER M. GRANHOLM
GOVERNOR

STEVEN E. CHESTER
DIRECTOR

February 4, 2004

Ms. Susan Carrington
Vice President and Director
Michigan Dioxin Initiative
The Dow Chemical Company
47 Building
Midland, Michigan 48667

Dear Ms. Carrington:

SUBJECT: Further Response to The Dow Chemical Company's (DCC's) Comments on the Tittabawassee River Aquatic Ecological Risk Assessment; MID 000 724 724

This is in follow up to the Michigan Department of Environmental Quality (MDEQ), Waste and Hazardous Materials Division (WHMD), response sent on January 20, 2004, regarding the comments you submitted on December 19, 2003, relative to the Tittabawassee River Aquatic Ecological Risk Assessment contracted by the MDEQ, Remediation and Redevelopment Division, and conducted by Dr. Hector Galbraith of Galbraith Environmental Sciences LLC (GES ERA, 2003). That letter indicated that the MDEQ would consider your comments in the context of the adequacy of the revised Scope of Work (SOW) for Remedial Investigation for the Tittabawassee River and Floodplain.

At the request of the MDEQ, Dr. Galbraith has reviewed the above-referenced comments (DCC [2003]) and provided his evaluation to the MDEQ. Additionally, after sharing the DCC comments on the GES ERA with the U.S. Environmental Protection Agency, Region 5 (U.S. EPA), on January 13, 2004, the MDEQ received an evaluation from the U.S. EPA on January 30, 2004. The purpose of this letter is to provide the results of these evaluations so they may be taken into consideration as the SOW is being finalized prior to the February 17, 2004, due date. The MDEQ concurs with these evaluations and believes that sufficient information is currently available from the GES ERA to make corrective action risk management decisions for the Tittabawassee River. We are attaching the comments from Dr. Galbraith and the U.S. EPA as Attachments A and B, respectively.

Should you require further information or wish to discuss these evaluations, please contact Ms. Cheryl Howe, Hazardous Waste and Radiological Protection Section, WHMD, at 517-373-9881 or by e-mail at howec@michigan.gov; or you may contact me.

Sincerely,

Original signed by

George W. Bruchmann, Chief
Waste and Hazardous Materials Division
517-373-9523

Attachments
cc: Dr. Hector Galbraith, GES
Mr. Greg Rudloff, U.S. EPA, Region 5
Mr. Greg Czajkowski, U.S. EPA, Region 5
Mr. Jim Sygo, Deputy Director, MDEQ
Mr. Andrew Hogarth, MDEQ
Ms. Liane Shekter Smith, MDEQ/Corrective Action File
Mr. Steve Buda, MDEQ
Ms. De Montgomery, MDEQ
Ms. Brenda Brouillet, MDEQ
Mr. Terry Walkington/Ms. Trisha Peters, MDEQ
Mr. Allan Brouillet, MDEQ
Ms. Ginny Himich, MDEQ
Ms. Cheryl Howe, MDEQ
Ms. Sue Kaelber-Matlock, MDEQ
Dr. Deb MacKenzie-Taylor, MDEQ
Mr. Al Taylor, MDEQ

Attachment A

Evaluation by Dr. Hector Galbraith, Galbraith Environmental Sciences LLC

1. GENERAL COMMENTS

Some of the DCC (2003) comments relate to typographical errors. These are not discussed in this document, but will be rectified in any future version of the GES ERA. The purpose of this review is to focus on the more substantive of the DCC (2003) comments. For the sake of clarity, the DCC (2003) comments have been grouped into eight categories. Each of these is dealt with below, followed by a summary of the main points of the review.

2. COMMENTS REGARDING SCREENING-LEVEL AND OTHER TYPES OF ERA

The DCC (2003) review refers to the GES ERA as a “screening level” or “Tier 1” assessment. Typically such assessments lack site-specific data regarding exposure levels to the selected receptors, or contaminant concentrations in the tissues of these receptors. Being so limited, they cannot address questions regarding the magnitude or spatial locations of risk at the site being investigated, but focus on the more preliminary question: can we safely ignore the possibility of unacceptable risk at the site? However, the GES ERA is not such an assessment. It does include site-specific data that describe dioxin and furan exposures to piscivorous wildlife (85 individuals of 4 species of fish collected from the Tittabawassee River), and piscivorous wildlife tissue concentrations (in eggs of wood ducks and hooded mergansers from the Shiawassee National Wildlife Refuge). These data clearly show that the piscivore food web in the assessment area is contaminated with dioxins and furans, and that these same contaminants are currently present in the eggs of at least two species of birds at levels sufficient to pose risk (see Section 9). If the GES ERA had not included these data it might be considered a “screening level” assessment. However, the fact that it does takes it beyond this category and provides results that can be used to confirm the existence of risk and inform remediation decisions.

3. THE USE OF REASONABLY PROTECTIVE PARAMETERS

DCC disputes the validity of the use of no observed adverse effects levels or concentrations (NOAELs and NOAECs) in the derivation of toxicity reference values (TRVs) and proposes that lowest observed adverse effects levels or concentrations (LOAELs or LOAECs), or a statistically derived value between the two, are more appropriate. The resolution of this difference of opinion hinges on what are considered to be reasonably protective parameters for use in this particular ecological and contaminant situation. The rationale for the identification and use of the TRVs in GES ERA is discussed below:

NOAELs and LOAELs

LOAELs are the lowest exposure concentrations in controlled experiments that resulted in adverse effects among the study organisms. Thus, a LOAEL is an exposure concentration that may be expected to cause adverse impacts among exposed organisms. NOAELs are the greatest exposure concentrations that did not result in adverse effects. Therefore, while NOAEL concentrations can be seen as unlikely to pose risk of adverse effects to exposed organisms, LOAEL concentrations are likely to pose such risks. If the TRVs used in an ERA are based on NOAELs they are more likely to be protective of the exposed fish or wildlife populations. In contrast, if the TRVs are based on LOAELs, they are unlikely to be sufficiently protective of individual organisms and, potentially, populations. It is correct, as stated in DCC (2003), that the use of NOAELs may at times be over-protective rather than reasonably protective; however the selection of NOAELs vs. LOAELs as TRVs in a risk assessment must take into account uncertainties regarding the toxicity of the contaminants and the sensitivities of the exposed organisms if the possibility of making false negative decisions is to be avoided.

There are three main areas of uncertainty in selecting reasonably protective TRVs in the aquatic ERA performed for the assessment area: first, the dose-response relationships of furans are relatively little understood. In particular, there is uncertainty regarding the shape of the dose-response curve for individual congeners. The dose response curves for dioxin-like compounds are typically steep and selecting a point between the LOAEL and NOAEL that is adequately protective of exposed organisms is problematic (since it is known where exactly this steep inflexion point occurs). If the point selected happens to be on the steep upward section of the curve, risks can be inadvertently missed. Second, relatively few organisms have been exposed to dioxins and furans in controlled laboratory tests. The vast majority of the wildlife species that inhabit the assessment area have not been tested and their sensitivities are, therefore, unknown. This is particularly so for furans which have received very much less scientific attention than dioxins. Nevertheless, it is furans that contribute most of the potential toxicity in the assessment area. It is known that some organisms are highly sensitive to dioxin-like contaminants, mink and domestic fowl for example, which if exposed to egg concentrations or dietary doses in the low parts per trillion may exhibit adverse responses. We know that mink could potentially inhabit the assessment area and be exposed. Also there is no scientific reason for concluding that some of the untested organisms that inhabit the assessment area might not be as, or even more, sensitive than the mink or fowl. Third, the studies on which the NOAELs and LOAELs are based were performed in the laboratory where the only stressor that the test organism experienced was that of the contaminant (typically only one congener). Organisms in the wild may be exposed to a host of additional stressors. Thus, extrapolation from the laboratory to the field regarding the potential risk of a particular exposure level involves uncertainty: a dose or dietary exposure level that was safe in the laboratory may not be so in the field. A recent U.S. EPA report (NCEA, 2003**)** points out that dioxin TRVs based on laboratory tests are typically higher than those based on field studies, indicating that dioxin effects in the field may be exacerbated**.**

Given the above uncertainties and the necessity to avoid false negative decisions arising out of the ERA, it is entirely appropriate that TRVs be based on NOAELs, rather than LOAELs or some hypothetical intermediate value. Only the use of NOAELs provides an adequate and reasonable degree of protectiveness. It should be noted, however, that even NOAEL-based TRVs may not be protective enough for all species since we know so little about the sensitivities of most of the wildlife species in the assessment area. The TRVs developed in the GES ERA are considered to be reasonably protective, given the prevailing uncertainties.

TRVs

One major uncertainty regarding the selection of TRVs from NOAELs for the assessment area is that we do not know how sensitive to dioxins and furans most of the organisms that inhabit the site are. For example, there are a number of largely piscivorous birds whose breeding ranges include the watershed (Brewer *et al*., 1991), and for which we have no test information. These include American bittern, least bittern, green heron, hooded merganser (known to be exposed to and contaminated in the assessment area with dioxins and furans), and belted kingfisher. It is also known that individual species may differ widely in their sensitivity to dioxin-like contaminants. If one or more individual species were selected solely as the focus of the GES ERA the risk of not being protective enough for more sensitive species or, conversely, being overprotective of less sensitive species would be incurred. In order to clarify the potential risks posed by contamination to all piscivorous birds at the assessment area the GES ERA did not focus on any one receptor species but instead developed from the scientific literature three ranges of sensitivity which were then used as TRVs. Thus, the GES ERA does not focus on any one species, but on “sensitivity guilds”. This avoids the problems of inter-specific differences in sensitivity and of not being protective of the majority of the species at the site (although wild species that may be more sensitive than the most sensitive of those tested may not be adequately protected by this procedure). Although risks were found to apply to all of the sensitivity categories (most, less, and least sensitive), it should not be concluded that *all* avian piscivores are at risk: some may be so insensitive as not to be at risk. Nevertheless, it was concluded that wild birds whose sensitivities conform to the most and less sensitive, and at least some with sensitivities in the category least sensitive are at risk.

DCC (2003) argues that this approach is not valid, is flawed, and overestimates risks because there is uncertainty regarding the interpretation of the studies on which the TRVs are based. This is not so: the approach used, by developing representative sensitivity ranges based on a number of test species rather focusing on only one or more “indicator organisms”, helps overcome exactly the interpretation problems that DCC (2003) correctly identifies.

DCC (2003) also states that 16 pg/g is a more representative dietary TRV for mink and river otter. This is based on a 2003 study by Bursian *et al*. This study is not published in a scientific journal but on the internet. This study has been obtained by GES and is currently being evaluated for its relevance to the Tittabawassee ERA. However, it should be noted that no less than 3 previous studies indicate that the dietary TRV for mink should be much less than this at 1-2 pg/g. These latter studies support the use of the 1 pg/g dietary TRV used in GES (2003).

4. THE GES ERA DID NOT REFER TO AMELIORATION OF TOXICITY AND "RECOVERY" OF BIOTA IN THE ASSESSMENT AREA

At various places in DCC (2003), for example at the 5th bullet on page 3, it is proposed that the GES ERA should have cited historically higher levels of PCDD/PCDFs in Tittabawassee River fish as evidence that the system is naturally recovering. This is irrelevant to the main purpose of the ERA which is to evaluate *current* risks. The likelihood that risks were even greater in the past, although interesting, is not the focus of the GES ERA.

5. DCC (2003) RESPONSES CITE POPULATION LEVELS OF WILDLIFE SPECIES IN ASSESSMENT AREA AS EVIDENCE OF NO RISK

At a number of places in DCC (2003), it is claimed that the existence of piscivorous wildlife in the assessment area is evidence that there must be little or no risk. This claim is based on an oversimplification of wildlife population responses to stressors, and a misunderstanding of how dioxins and furans exert their effects. Chemically-impaired reproductive success does not necessarily imply that populations will be reduced, particularly in areas experiencing recruitment from elsewhere. It has been shown in numerous studies that organisms may recruit into an area, even when they consequently suffer adverse impacts. This is the basis for the "source-sink" phenomenon observed in population ecology. This recruitment may keep the population levels high, thereby masking the effects of the stressor. Thus, simple presence-absence data, population counts, or density estimates may tell us little about the conditions experienced by the organisms at a particular site. Also, no data to support the contention of the presence of stable or recovering populations, beyond the simple representation that such populations exist, is presented in DCC (2003). An exception to this is some statements regarding reproductive performance of bald eagles in the Saginaw Bay watershed (page 27 of DCC, 2003). However, no evidence is cited that any of these birds obtain significant components of their reproductive season diet from the Tittabawassee River downriver of Midland.

6. OTHER TECHNICAL ISSUES

A number of technical points (in addition to those addressed above) were raised in DCC (2003). These are discussed below:

Size of fish eaten by piscivorous wildlife. It is claimed in DCC (2003) that the larger fish sampled by MDEQ would not be eaten by mink. However, this disregards the fact that part of the mink diet could well be carrion and could thereby include such large fish. Also, river otters will take larger fish than mink. It is not safe to conclude that only smaller fish will be eaten by piscivorous mammals (and by birds such as bald eagles that frequently consume carrion). Also, fish down to approximately 3 inches in length were sampled by MDEQ. These (particularly gizzard shad) were heavily contaminated by dioxins and furans.

Invertebrate sampling. The DCC (2003) comments criticize the GES ERA by claiming that MDEQ had originally intended to sample invertebrates and include them in the evaluation. This is not the case. The invertebrates that MDEQ proposed to sample were intended for the forthcoming terrestrial ERA and had no relevance to the GES aquatic ERA.

The use of wood duck and hooded merganser eggs to calculate site-specific BMFs. DCC (2003) asserts that it would have been more valid to use the wood duck and hooded merganser eggs from the Shiawassee NWR to calculate site-specific BMFs, rather than rely on data from the scientific literature. We agree that site-specific data are generally preferable, but did not calculate such BMFs for three reasons: first, the sample sizes for the ducks are too small to allow reliable estimation of BMFs for the ERA. Indeed, their main purpose for the ERA was not to calculate BMFs, but only to confirm that dioxins and furans were being bioaccumulated by piscivorous birds. Disregarding the limitations of this small sample size, DCC (2003) calculates BMFs from the wood duck and hooded merganser data to establish alternative risk levels (see Section 7).

Second, the wood duck and hooded merganser egg data should be viewed with some caution since there is reason to believe that there is a possibility that eggs may have been confused during sample collection, transfer, or analysis. The results show that one of the Shiawassee NWR hooded merganser eggs has anomalously low TCDD-EQ concentrations, while one of the wood duck eggs from the reference area has anomalously high concentrations. It is possible that these eggs may have been transposed during sample collection, transfer, or analysis. If this is so, the DCC (2003) calculations considerably underestimate the site-specific BMFs and, therefore, risk to piscivores. This is another reason for the GES ERA adopting the more conservative approach of only using these eggs to show that dioxin and furan contamination extended through the food chains to piscivorous predators, rather than using them to calculate site-specific BMFs.

Lastly, the GES ERA focused on piscivorous birds. Wood ducks eat a variety of aquatic prey and fish may be a relatively minor component of their diet. Therefore, using site-specific BMFs calculated from this species to model risks in piscivores would be misleading. The elimination of wood duck reduces the already small sample size yet further.

The use of "secondary literature" to derive TRVs. DCC (2003) asserts that secondary values (i.e., values derived in previous Great Lakes ERA from primary [experimental] results) were used to derive TRVs for piscivorous mammals. This was not the case; the TRVs were derived from the experimental results, while the previously used TRVs were only cited to show that our results agreed broadly with those of other experts in the field.

The fact that walleye were not included in the risk calculations. As DCC (2003) points out, MDEQ caught walleye during their fish capturing effort, but these fish were not included in the GES ERA calculations. The walleye that were caught were spring-run fish and it was felt that since they had only recently arrived in the assessment area their body burdens of dioxins and furans would not reflect the levels that piscivorous wildlife would have been exposed to during the period of oogenesis or parturition.

Saginaw River and Bay. DCC (2003) disputes the prediction of the GES ERA that risk to piscivorous wildlife from dioxins and furans may pertain within Saginaw River and inner Saginaw Bay. This prediction was based on sediment threshold concentrations calculated using data from the Tittabawassee River and sediment data from the Saginaw River and Bay. Given the available data, we agree that it cannot be definitely determined that risks to piscivores occur in the Saginaw River and Bay, however, the data that do exist show that such risk cannot be safely discounted. Further sampling, particularly of sediments and biota, are necessary before this can be confirmed or discounted.

7. HAZARD INDICES CALCULATED BY DCC

In addition to criticizing the GES ERA, DCC (2003) also presents hazard indices (HIs) based on what they apparently consider to be more appropriate parameters. The resulting HI values for piscivorous birds range from 1.3 (least sensitive species) up to 26 (most sensitive). These alternative HIs are flawed and not adequately protective since they are developed from biomagnification factors (BMFs) derived from wood duck and hooded merganser eggs from the Shiawassee National Wildlife Refuge. As explained above in Section 6, this procedure is not valid. Also, possible transposition of eggs may have occurred in the laboratory analyses (See Section 6), thereby underestimating contaminant uptake and, consequently, levels of risk. The wood duck and hooded merganser eggs in the GES ERA were, more appropriately, used only as confirmation that the food chains and the receptors were exposed and contaminated. Nevertheless, even after using inadequately protective parameters, the risk level (as indicated by the HIs) remain above the safety threshold (HI=1) for all three sensitivity groups.

A similar DCC (2003) calculation for piscivorous mammals based on a dietary NOAEL value of 16 pg/g results in a river otter HI of 3.2 (100% fish diet) and HIs for mink that range from 3.2 to <1 (mink would have to consume less than 30% of their diet as Tittabawassee River carp, walleye, catfish, shad, and bass to reduce their HI to 1 or less). This analysis underestimates the actual risk level in the assessment by including walleye in the fish tissue samples. As already indicated (Section 6), MDEQ considers that the walleye were spring-run fish and only recently arrived in the assessment area. By including fish that have not been exposed for long to Tittabawassee River levels of dioxin or furan contamination, and over-representing the contribution of summer river walleye populations to mink diet, the resulting HIs are underestimated.

The 16 pg/g TRV used by DCC (2003) was obtained from a report thus far only published on the internet and that has not (so far as we are aware) undergone the scientific peer review process necessitated by publication in a scientific journal. This study has been obtained by GES and is currently being evaluated for its relevance to the Tittabawassee ERA. However, it should be noted that no less than 3 previous experimental studies indicate that the dietary TRV for mink should be much less than this at 1-2 pg/g. These latter studies support the use of the 1 pg/g dietary TRV used in the GES ERA.

In summary, the DCC (2003) analyses show that even when insufficiently protective parameters are used, it must be concluded that risks are still posed to piscivorous wildlife in the assessment area.

8. DCC PROPOSALS FOR ADDITIONAL ERA

Throughout DCC (2003), reference is made to future risk assessment activities planned by DCC and its consultants. A component of these proposed activities is, apparently, to perform field studies of the population biology and demographics of ecological receptors in the Tittabawassee River and its floodplain. The DCC apparently anticipates that the results from these studies will refine the results of the GES ERA (and any future ERA estimations) in a "weight of evidence approach". The fact that the MDEQ did not perform such studies is pointed to by DCC as evidence that the GES ERA cannot be considered definitive.

Underlying this claim is the rationale that the predictions of the GES ERA involve uncertainties regarding actual impacts in the field, and that these can be minimized or removed by performing field population studies. While there is no doubt that field population studies can provide valuable information, they are not necessarily a "silver bullet" that will remove uncertainty. In fact, they may only add additional uncertainties. This is because natural and uncontrolled variation in the field can make it very difficult to be completely sure about identifying and teasing out cause and effect. At the heart of this are difficulties that population ecologists have been wrestling with for decades: what constitutes "natural" variability and how does it vary temporally and spatially; how can a signal be detected against the high degree of "noise" from natural background variability; how can confounding factors be controlled; what is a "natural" baseline against which to measure "impacts"? Unless carried out over many years and with strenuous efforts made to control confounding factors, field studies often lack the precision necessary to address these questions.

This is especially so with field studies of contaminants (like dioxins and furans) that typically exert relatively subtle effects. Contamination of the environment by dioxins and furans does not typically result in adult mortalities among wildlife that can be quantified by simple body counts. Dioxins and furans do affect adult organisms, but mainly by reducing their reproductive performance. This can be much more difficult to unambiguously measure in the field and assign to one cause since it may naturally vary depending on season, habitat quality, the age and quality of the organisms, predators, weather, microclimate, and a large number of other confounding variables that are likely to be extremely difficult to tease apart with any certainty. Also, organisms differ in their relative sensitivities to dioxins and furans: some such as the wood duck are apparently very sensitive while others such as tree swallows are not. For the vast majority of wildlife species we have no information regarding their degree of sensitivity. Any field study should focus on sensitive species if false negative results are to be avoided. This constraint adds further difficulties to performing field studies that will not introduce yet more uncertainty into the ERA decisions.

In summary, unless strictly controlled and carried out over a large number of years and with large sample sizes, it should not be assumed that performing studies in the field will automatically significantly reduce the uncertainty associated with predicting ecological risks.

9. DCC CONCLUSIONS OF NO OR LOW RISK

Using the various alternative approaches criticized above, DCC (2003) recalculated HIs for piscivorous birds and mammals in the assessment area. The result of this is that the HIs are lowered in comparison to those reported in the GES ERA. However, even given that the approaches used lack sufficient degrees of protectiveness, the DCC (2003) estimated risk numbers are not negligible, and should result in the conclusion that risk is posed to ecological receptors in the assessment area. Also, DCC (2003) used the wood duck and hooded merganser egg data from the Shiawassee NWR to calculate site-specific BMFs. When these same data are used to calculate HIs the results for hooded mergansers vary up to more than 120 and those for the wood duck to 49. Thus, actual empirical data from the assessment area confirm, despite that they are based on only small sample sizes, the existence of high levels of risk.

10. SUMMARY

This review has shown that the criticisms leveled at the GES ERA in DCC (2003) are invalid. Specifically:

- Both dietary and bird egg contaminants data were included in the analysis and they clearly indicate risk to ecological receptors. This level of sophistication transcends “screening-level” ERA and provides a basis for remediation decisions.

- Given the levels of uncertainty associated with the toxicity of furans to wildlife and the unknown sensitivities of many piscivorous wildlife species in the assessment area, the use of NOAELs in the development of TRVs is reasonably protective. The use of LOAELs or some intermediate point would be less so.

- GES agrees that the risks posed by dioxins and furans to wildlife in the assessment area may have been even higher in the past. However, this and the contention that the area is “recovering” is irrelevant to the GES ERA which focuses on current risks.

- The assertion in DCC (2003) that the existence of wildlife populations in the assessment area testifies to no or to only minimal risk is unsupported by any data. Furthermore, reproductive impacts due to dioxins and furans would not necessarily result in reduced populations.

- Due to small sample sizes, a potential transposition problem with the wood duck and hooded merganser egg data set, and the non-fish diet of wood ducks, it is not appropriate at this stage to develop site-specific BMFs for piscivorous birds.

- Despite their criticisms and the use of inadequately protective procedures, HIs calculated by DCC (2003) also indicate risk to ecological receptors in the assessment area.

- In their assertions of little or no risk at the site, the DCC ignores the fact that the TCDD-EQ concentrations measured in the hooded merganser and wood duck eggs (actual empirical data) confirm risk to receptors.

- DCC (2003) proposes that further ERA be performed in the assessment area and that a component of this should be field studies of impacts to receptors. According to DCC (2003) the results of this will reduce the uncertainty associated with the GES ERA. While field studies can provide valuable information, it is the recommendation of GES that the MDEQ should view this proposal cautiously. Unless they are carried out over many years and with strenuous efforts made to control confounding factors, field studies often result in adding yet more uncertainty or only in replacing one set of uncertainties with another.

- Available data suggests that dioxins and furans in Saginaw River and Saginaw Bay sediments may pose risks to piscivores. We agree with the DCC that the confirmation of this risk requires further sampling. However, the data that are available strongly suggest that the possibility of such risk cannot be discounted.

11. REFERENCES

Brewer, R., G.A. McPeek, and R.J. Adams. 1991. *The Atlas of Breeding Birds of Michigan*. Michigan State University Press, East Lansing, MI.

DCC, 2003. The Dow Chemical Company's Review of the Tittabawassee River Aquatic Ecological Risk Assessment: Polychlorinated dibenzo-*p*-dioxins and Polychlorinated dibenzofurans. Dow Chemical Company, December 2003.

GES, 2003. Tittabawassee River Aquatic Ecological Risk Assessment: Polychlorinated dibenzo-*p*-dioxins and Polychlorinated dibenzofurans. Galbraith Environmental Sciences, Newfane, VT.

NCEA, 2003. Analyses of Laboratory and Field Studies of Reproductive Toxicity in Birds Exposed to Dioxin-Like Compounds for Use in Ecological Risk Assessment. U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, Cincinnati Office , Cincinnati, OH, EPA/600

Attachment B
Evaluation by the U.S. Environmental Protection Agency, Region 5

The MDEQ also received the following from Mr. Greg Czajkowski with the U.S. Environmental Protection Agency, Region 5 (U.S. EPA), Waste Pesticides and Toxics Division, in response to DCC's position that "Under EPA Guidelines for Conducting an ERA, the Michigan DEQ Tittabawassee River Aquatic Ecological Risk Assessment can only be considered a screening level ERA." Further, the DCC concludes that no management decisions can be made without further refining of the risk assessment.

According to U.S. EPA guidance found in the document entitled "Example Work Plan To Perform a Screening Level Ecological Risk Assessment at a Hazardous Waste Combustion Facility" written by Daniel J. Mazur, U.S. Environmental Protection Agency, Region 5, February 1999, the U.S. EPA has established a three-tiered approach (Tier 1, Tier 2, and Tier 3) for performing ecological risk assessments. This tiered approach is designed to be an iterative process, with each successive tier requiring the incorporation of more site-specific information and increasing in complexity. This tiered process, therefore, provides a means of progressively refining the scope and focus of the ecological assessment, if warranted, by using more site-specific data in place of conservative assumptions to characterize risk.

The Tier 1 level of effort is termed the Screening Ecological Risk Assessment (SERA). The SERA provides an initial evaluation of potential ecological risks using generally conservative assumptions. The conservative assumptions are intended to ensure that risks will not be underestimated at a site. The SERA is typically referred to as a "desktop" effort since it involves little or no field or on-site work.

The Tier 2 effort in the ecological risk assessment process is termed the Preliminary Ecological Risk Assessment (PERA). The PERA incorporates information obtained from the SERA with additional information gathered through limited field work. This field work typically consists of a qualitative ecological reconnaissance such as wetland delineation and may include some limited environmental media sampling.

The Tier 3 effort is termed the Detailed Ecological Risk Assessment (DERA). The DERA incorporates information from the SERA and PERA, but with a much more focused level of effort. The DERA is much more quantitative in nature and typically includes laboratory studies and/or field studies. Biological field surveys are frequently conducted in conjunction with toxicity testing in order identify specific stress agents responsible for observed impacts.

Although each successive tier of the ecological risk assessment process is more comprehensive than the previous tier, the basic framework and components for each tier are the same. Specifically, each tier contains the same three components central to the ecological risk assessment process: problem formulation, analysis, and risk characterization. The problem formulation component is a systematic planning component that includes the: 1) definition of the purpose and scope of the ecological risk assessment; 2) characterization of the ecological resources in the surrounding area; and, 3) preliminary identification of stressors of potential ecological concern. The second component of the ecological risk assessment is the "analysis" which includes a characterization of potential exposures by ecological receptors to stressors and the potential adverse ecological effects associated with exposure to stressors. The third component is termed "risk characterization" which integrates the results of the exposure and effects analyses to evaluate the likelihood of adverse ecological effects associated with exposure to stressors. It includes a summary of the assumptions used and the scientific uncertainties of the risk analysis, along with conclusions.

It has been the U.S. EPA Region 5's experience based upon the review of numerous ERA's, that the level of effort in each ERA tier or iteration varies from site to site and depends upon the amount of available site-specific information. Sometimes the line between a strict screening level assessment (SERA) and a more detailed preliminary ecological risk assessment (PERA) is blurred.

The MDEQ risk assessment goes beyond a basic screening level ERA by bringing in site-specific sampling data for various wildlife found in the study area to utilize multiple lines of evidence to estimate potential risk. As indicated above, EPA guidance suggests that for each successive tier of an ERA, the following basic components are included: 1) problem formulation; 2) analysis; 3) risk characterization; and 4) uncertainty analysis. The MDEQ's risk assessment has addressed each of these areas and is consistent with the 1998 EPA guidance for conducting ecological risk assessments.

The primary goal of the ERA is to determine the likelihood of harmful effects to animals and plants both on-site and off-site that are exposed to site-related hazardous chemicals (referred to as a significant risk). Since the ERA process is iterative, the analysis phase uses more site-specific information at each successive stage or tier. The objectives, however, remain the same in each tier, e.g.: make a determination that: 1) a remedial action is required; 2) further tier evaluation is necessary; or 3) there is acceptable risk.

It is important to note that there is nothing in the U.S. EPA's guidance to preclude making a decision to remediate or implement interim corrective measures at the Scientific Management Decision Point (SMDP) at any tier in the risk assessment. The risk assessment process can be concluded at any stage provided there is adequate information to support the finding of an unacceptable level of ecological risk. The U.S. EPA guidance found in ECO Update Publication 9345.0-14, EPA 540/F-01/014, June 2001 on the role of the SLERA reaffirms that a screening level assessment, while abbreviated, is nonetheless a complete risk assessment. Regardless of the findings of the SMDP occurring after Step 2 (i.e., further assessment or no further assessment required), each SLERA should include documentation supporting the risk characterization and uncertainty analysis.

Pursuant to the U.S. EPA's publication entitled "Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments - Interim Final" (http://www.epa.gov/oerrpage/superfund/programs/risk/ecorisk/ecorisk.htm), "Ecological risk assessments can have their greatest influence on risk management at a site in the evaluation and selection of site remedies. The ecological risk assessment should identify contamination levels that bound a threshold for adverse effects on the assessment endpoint. The threshold values provide a yardstick for evaluating the effectiveness of remedial options and can be used to set cleanup goals if appropriate.

To justify a site action based upon ecological concerns, the ecological risk assessment must establish that an actual or potential ecological threat exists at a site. The potential for (i.e., risk of) impacts can be the threat of impacts from a future release or redistribution of contaminants, which could be avoided by taking actions on "hot spots" or source areas. Risk also can be viewed as the likelihood that current impacts are occurring (e.g., diminished population size), although this can be difficult to demonstrate. For example, it may not be practical or technically possible to document existing ecological impacts, either due to limited technique resolution, the localized nature of the actual impact, or limitations resulting from the biological or ecological constraints of the field measurements (e.g., measurement endpoints, exposure point evaluation). Actually demonstrating existing impacts confirms that a "risk" exists. Evaluating a gradient of existing impacts along a gradient of contamination can provide an stressor-response assessment that helps to identify cleanup levels. As noted above, the ecological risk assessment should provide the information needed to make risk management decisions (e.g., to select the appropriate site remedy)."

It is the responsibility of the Risk Manager to evaluate the risk described by the risk assessor and decide on the proper course of action.